02N-0276

Dockets Management Branch (HFA - 305)

Berne, April 04, 2003

our ref.: zim / # 365831.2

Food and Drug Administration (FDA)
5630 Fishers Lane, Room 1061
Rockville, MD 20852
USA

Registration of Food Facilities and Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Proposed Rules

Comments submitted by Switzerland

Dear Sir or Madam:

We refer to the WTO notifications G/TBT/N/USA/31; G/SPS/N/USA/690; G/SPS/N/USA/691 as well as to the notice of proposed rulemaking published in the U.S. Federal Register on February 3, 2003. Regarding the draft provisions on sections 305 and 307 of the U.S. Bioterrorism Act, Switzerland would like to submit the following comments[1]:

General Remarks

Switzerland shares the U.S. concerns about possible bioterrorist threats and thus understands the U.S. objective in formulating a strategy to enhance the security so as to protect its citizens from the threat of bioterrorism or related emergencies. We are, however, concerned that the proposed U.S. measures, including mandatory registration of food facilities and prior notice of imported food shipments, would significantly impede international trade in food while not significantly contributing to the level of protection targeted by the U.S.

Switzerland agrees with the U.S. that a potential strike on the food supply, though having a very low probability, could trigger very high costs. It is thus understandable that the U.S. government desires to dispose of effective tools with a view to deterring a possible outbreak and to limiting the consequences of such an outbreak. However, Switzerland is not convinced that the proposed measures are adequate in providing the maximum level of protection against bioterrorist attacks involving the food supply.

While the proposed measures will not be able to deter a possible strike on the food supply, we recognize that instruments such as registration and record-keeping may play an important part in limiting the effects of an outbreak by facilitating recall procedures and the identification of the "point of contamination". Thus, the Swiss authorities are not opposed to registration of facilities (Section 305) and record keeping requirements in principle, provided that they are applied in a non-discriminatory manner, are not excessively burdensome to foreign facilities and respect both national sovereignty and business / trade secrets.

Switzerland, however, has strong reservations about the adequacy of the prior notice to imported food

[1] An advance copy of this letter has been transmitted to FDA on April 04 2003 by E-Mail (fdadockets@oc fda.gov) The signed original version will be sent by regular mail. Copies of these observations will in parallel be submitted to US trade authorities responsible for the WTO TBT and SPS notification procedure (ref.: G/TBT/N/USA/31; G/SPS/N/USA/690; G/SPS/N/USA/691) as well as to the U S embassy in Bern

Effingerstrasse 1, CH-3003 Bern
Tel. 031 324 08 47, Fax 031 324 09 59

02N-0276 C109

requirement (Section 307). Since customs procedures have already been tightened[2] to respond to possible bioterrorist threats, Switzerland is of the view that further reinforcement of the rules on documentation requirements and prior notice of shipments upon importation would duplicate existing measures.
With regard to these separate but connected initiatives of FDA and customs authorities Switzerland is concerned that an uncoordinated introduction of measures may in addition have the potential to create confusing or conflicting requirements, which may lead to errors and omissions due to slight inconsistencies.

From the U.S. explanations we understand that the prior notification requirement is needed because the existing customs systems cannot be modified to accommodate the additional data requirements prior to the December 12 deadline. In this context we feel rather disconcerted that the burden of a duplicative notification system must be born by foreign producers and exporters. We thus believe that it is the responsibility of the U.S. authorities to coordinate their objectives and approaches in order to ensure consistency between the requirements.

Furthermore it has to be noted that requirements, such as registration of facilities and prior to shipment notice are extremely burdensome in terms of labour, time and cost.

In conclusion, we feel that the proposed rules and in particular the provisions in section 307, if enacted, would be discriminatory, disproportional and more trade-restrictive than required to achieve the stated objective.

With respect to international trade, the United States affirm in their Federal Register publication that in establishing and implementing the proposed rules FDA will fully comply with its international trade obligations, including the applicable World Trade Organization agreements. Switzerland does not share this conclusion for the reasons indicated in this letter and looks forward to hearing further explanations on the issue within the respective WTO Committees.

Specific Comments

Section 305 (Registration of Facilities)

As stated in the introductory section, Switzerland agrees that a register of facilities combined with traceability elements may facilitate action in response to an emergency situation. However, we fail to see why it would for this purpose not be sufficient to require food facilities to keep documentation (one step forward, one step back) without their prior formal registration with FDA. There is no indication that a documentation system without formal registration would be inappropriate or ineffective to achieve the stated objective.

Furthermore, Switzerland is concerned about the amount of information that has to be disclosed by food facilities in the proposed process of registration. Some of this information has to be considered as commercial information, which may only be required if the measure is justified by a strong public interest. In any case, information provided by food facilities must be kept confidential, must not be used for other purposes than for the stated nor be disclosed to the public. Switzerland is interested to know how the FDA intends to secure the information received in the process of registration.

[2] Container Security Initiative (CSI)

Proposed § 1.225 (b)

FDA is seeking comments on whether the agency has authority to exempt domestic facilities engaged only in intrastate commerce from the registration requirement and if so whether the agency should use that authority. Taking into account the fundamental WTO principle of non-discrimination (i.e. national treatment) it is the view of Switzerland that FDA may not exempt domestic facilities engaged only in intrastate commerce from the registration requirement. In addition, such an exemption would not be justified since a possible threat may also arise from such establishments.

Proposed § 1.225 (c) and § 1.227 (12)

Since Swiss food facilities exporting products to the U.S. often work together with U.S. importers, it is essential that the latter qualify as U.S. agents and be allowed to assume all rights, duties and responsibilities given to U.S. agents.
Given that foreign food facilities in some cases work together with more than one importer (depending on the product) we suggest to provide foreign facilities with the possibility to designate more than one U.S. agent.

Proposed § 1.226 (a)

The proposed rules include food establishments that only affix a label on the product in their definition of "facility" and consider labelling to be covered by the term "manufacturing/processing". However, when it comes to exemptions from the requirements for foreign facilities, labelling is not considered to be a "manufacturing / processing" step that allows exemption of the previous establishments.
Switzerland believes that this provision is not consistent in itself and proposes to reconsider the rule.

Proposed § 1.226 (g)

It is our understanding that facilities, regulated exclusively by the U.S. Department of Agriculture under the Federal Meat Inspection Act, the Poultry Products Inspection Act and the Egg Products Inspection Act are exempt from the registration requirement.
In this context, we do not see why the U.S. government establishes strict requirements on the one hand, but on the other exempts a considerable part of the production chain from these requirements.

Proposed § 1.227 (4)

We note that the definition of "food" and consequently the scope of the regulations is extensive. Taking into account the proposed exemptions of certain foodstuffs under § 1.226 (g) above, Switzerland questions for example the coverage of "pet food" within the public health and security objective.

Proposed § 1.227 (9)

Switzerland notes that the proposed definition of "port of entry" for the purposes of the Bioterrorism Act does not correspond to the U.S. customs port of entry. We are concerned that this divergence in approach leads to an additional duplicative "clearance" procedure, which we consider to be an unnecessary burden to international trade. As stated within the general remarks we consider it to be the responsibility of U.S. authorities to coordinate their requirements and to ensure that any measure is the least trade restrictive means to achieve the public health security objective.

Proposed § 1.230

According to this draft provision foreign facilities are required to register with FDA before they begin to manufacture/process, pack, or hold food for consumption in the United States.
This provision is in our view problematic, since at the time of manufacturing/processing (e.g. ,wine) it may often not be clear what country the product will be produced for. Therefore, Switzerland suggests that the appropriate time for foreign facilities to register would be before they export any products to the U.S. Since registration is a precondition for the importation of foreign products, we do not see the reason for requiring registration before a business-link to the U.S. has been established.

Proposed § 1.231

Switzerland welcomes the possibility of electronic registration that will be available 24 hours / day and 7 days / week. However, we do have some concern about the security of the data which will be transmitted to the FDA by this electronic system. What kind of security devices is FDA planning to use?

In the explanations of the act it is noted that registration by regular mail may take several weeks to several months, depending on the efficiency of the mail system and the number of paper registrations that FDA will need to enter manually into the system.
Although we fully understand that FDA wishes to encourage electronic registration we are of the view that it is the responsibility of FDA (at least at the initial implementation stage of the provisions) to provide for adequate resources in order to duely process registrations that have been filed by regular mail. We therefore request that FDA establishes transparent procedures for the handling of registrations submitted by regular mail.
Furthermore, FDA should, analoguous to the electronic system, grant immediate registration if all the data required has been submitted. The registration number should be given to facilities immediately after reception of the completed form.

We note that the rules are planned to come into effect on December 12, 2003. Given the fact that the final rules will only be published 2 months in advance of their entry into force and considering the time frames involved in international trade in food (the timeframes between the shipping of the product and its arrival at a U.S. port of entry), Switzerland is concerned, that the implementation period is too short to allow a smooth adjustment of procedures. According to international trade obligations, WTO members shall allow a reasonable interval between the publication of the final rule and its entry into force in order to allow time for producers and other facilities concerned to adapt their procedures to the requirements of the importing Member. Switzerland believes that an eight weeks implementation period can not be considered to be a "reasonable interval".

With regard to paragraph (d) we suggest that FDA also accepts registrations in other major languages commonly used in international trade, such as French, Spanish and German.

Proposed § 1.232 (b)

There is, in our view, no additional value in requesting disclosure of information about group structures and affiliated corporations. We therefore ask FDA to delete this section from the registration requirement.

Proposed § 1.232 (c)

Switzerland understands the U.S. wish to use inclusive contact details allowing for rapid communication in a possible emergency situation. However, we do not believe that it is neither necessary nor appropriate to request "private" contact details, such as home address and phone numbers, of the contact person.

Considering the legal consequences of non-compliance with regard to the obligation to keep registration details up to date this requirement would in our view go too far. It would require an adjusment of the registration each time a contact person changes home address and/or private telephone number.

Proposed § 1.232 (e)

Section 305 of the Bioterrorism Act states that FDA may require registrants to submit the general food categories of a food product at the facility, if FDA determines through guidance that such information is necessary.
We understand that FDA is interested in receiving comprehensive information about a company's activities. However, we do not believe that the reasons put forward by FDA (possibility for alerts, verification of imported food, direct communication) for requesting such information do justify the disclosure of detailed information on business activities, such as the nature of the food that is being produced and/or processed.

Switzerland, therefore, requests that the proposed registration does not include information on food categories produced or processed by a facility. A possible alternative would be to include another section of "optional" information.

Proposed § 1.234

The provisions under this paragraph require (by penalty) to update any information within 30 days. Switzerland doubts that this requirement will in practice ensure that all the registered information is up to date. We therefore suggest, that via the electronic registration system a reminder will be sent to registered facilities or their respective U.S. agent periodically with the request to update any information, as appropriate.

Proposed § 1.241

If a foreign food facility fails to register, their shipment will not be allowed entry to the U.S. before registration has been completed. Switzerland is concerned that the entire burden of proof lies with the facility. This may in our view be problematic, especially in the case of registration by regular mail.
Additionally, we would like to request information on how FDA plans to ensure that rapid clearence (of special importance in the case of perishable products) will be granted.

Section 307 (Prior Notice of Imported Food Shipments)

As noted in the introductory section, Switzerland is of the view that the prior to food shipment notice is a major additional financial and administrative burden to those involved in international food trade. No comparable requirements exist for domestic facilities, conducting business within the U.S.
We fail to see, how such a measure would offer any additional protection against a would-be criminal or terrorist, determined to spread some form of contamination. Firstly, neither the registration requirement nor the prior notice to imported food shipments are designed to ensure that the information which has been submitted is true. Anyone can submit false information and consequently "gain access" to U.S. markets.
Secondly, food shipments not falling within the FDA's area of competence (meat, chicken, eggs) are exempt from the requirements.
Due to existing loopholes, there will be enough possibilities for anyone determined to conduct a bioterrorist act on the U.S. by means of imported or domestically produced food.
Another aspect relates to domestic trade. While U.S. food facilities will also have to register with FDA they are not obliged to give FDA notice of their product being distributed on the U.S. market. As the prior notice

requirement is very costly, we consider it to be an unjustified discrimination. There is no objective reason, why foreign food facilities are considered "more dangerous" than domestic facilities. No indication suggests that a bioterrorist act would more likely involve imported products.

Proposed § 1.285

For Swiss food facilities it is of paramount importance that the prior to shipment notice can be submitted by their purchaser or importer. Since the system most likely will cause many difficulties in implementation, it is important that the consignee is authorised to submit any information.

Proposed § 1.286

The draft provisions propose that prior notice should be submitted to the FDA no later than noon of the calendar day before the day the article of food will arrive at the boarder crossing in the port of entry. In international transport there are always "unknowns", so that the requirement for accurate notification of arrival time and port is unrealistic. It must therefore be ensured that an inconsistency in time (and port) does not automatically lead to refusal of entry and thus to additional expenses (storage, delay expenses) if the incoherence can be justified (e.g. notification is corresponding to anticipated data). In this respect the provisions in § 1.294 are in our view overly restrictive, as they require an update of the notification if the time of arrival is more than 3 hours later or more than 1 hour earlier than the anticipated time of arrival.

FDA does not allow notification more than 5 days before the anticipated date of arrival at the port of entry, due to administrative reasons. As the prior notice requirement as a whole is most burdensome to foreign food facilities already, Switzerland is of the view that with respect to timing of the notification the most flexible solution should be granted.

In addition, we are concerned that the requirements of the Container Security Initiative may conflict with those of the Bioterrorism Act. It is therefore indispensable that the U.S. authorities ensure that all the necessary data can in practice be made available within the given timeframe.

Proposed § 1.287

These provisions allow prior notice only through electronic means. Although we understand that the prior notice must be submitted by the U.S. importer or consignee, we feel that this requirement is too restrictive. There should be provisions that allow submission of prior notice by fax or regular mail.

Proposed § 1.288

Switzerland notes that the information required in the prior notice form is extensive. We are of the view that not all information required is necessary in order to achieve the stated objective. Especially information about the grower and the consignee seems superfluous, as complementary documentation requirements (section 306) will be proposed.

Given the amount and detail of information requested by FDA we would like to obtain further information on how FDA plans to secure this information.

In conclusion, Switzerland considers the prior to shipment notice requirement (section 307) to be disproportionate and more trade-restrictive than necessary to achieve the stated objective. We, therefore, question the measure's consistency with international trade obligations and would like to ask the U.S. for further explications in this regard.

Switzerland appreciates your taking into account the comments above and is very interested in the U.S. authorities' response to the concerns raised.
Furthermore, the Swiss authorities would like to inform the FDA that additional comments will be provided once the provisions regarding Sections 306 and 308 are published.

If you have further questions, please do not hesitate to contact us.

Sincerely yours,

State Secretariat for Economic Affairs

Oscar Zosso
Ambassador

copy: Swiss Embassy, Washington
U.S. Embassy, Bern
USTR; U.S. Permanent Mission to the WTO (TBT and SPS Divisions), Geneva